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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/761,143	01/16/01	NAIR M	MSU 4.1-541

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HM12/1030

EXAMINER	
PATTEN,P	
ART UNIT	**PAPER NUMBER**
1651	10

DATE MAILED: 10/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

6150400

Office Action Summary

Application No.	Applicant(s)
09/761,143	Nair et al.
Examiner	**Art Unit**
Patricia Patten	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 2, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 3-6, 15-18, and 27-34* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3-6, 15-18, and 27-34* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☒ Interview Summary (PTO-413) Paper No(s). 9
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claims 1, 3-6, 15-18 and 27-34 were presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-6, 15-18 and 27-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly amended claims appear to recite New Matter which was not disclosed in the Instant Specification as originally filed. The newly amended claims are drawn to a method for inhibiting cyclooxygenase or prostaglandin H synthase via providing a mixture of cyanidin and an anthocyanin, or a method for inhibiting inflammation in a mammal comprising administering a mixture of cyanidin and an anthocyanin or a method for inhibiting inflammation via administration of a mixture of cyanidin and a bioflavanoid. Such a specific mixture, i.e., cyanidin with one bioflavanoid, or cyanidin with one anthocyanin cannot be found in the original disclosure and

therefore constitutes New Matter. Applicant is asked to amend the claims in order to omit the New Matter, which will overcome this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-6, 15-18 and 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lietti et al. (GB 1,598,294) in view of Wurm et al. (1982).

Claims 1, 3-6, 15-18 and 27-34, as amended, are drawn to methods for inhibiting cyclooxygenase or prostaglandin H synthase with a mixture of cyanidin and an anthocyanin, a method for inhibiting inflammation comprising administration of a mixture of cyanidin and an anthocyanin, and a method for inhibiting inflammation comprising administration of a mixture of cyanidin and a bioflavanoid. Claims are further drawn to where the cyanidin is obtained from sweet or tart cherries, wherein the method is performed in-vivo or in-vitro, wherein the cyanidin is incorporated into a dried mixture of isolated anthocyanins, bioflavanoids and phenolics along with a food grade carrier, wherein the carrier is a dried cherry pulp, wherein the ratio of dried mixture

to carrier is between about 0.1 to 100 and 100 to 0.1 and wherein the cyanidin is incorporated into a food.

Lietti et al. (GB 1,589,294) disclosed that anthocyanidins, and specifically cyanidin possessed anti-inflammatory activities (pp.1, lines 11-33 and especially 'cyanidine' structure).

Wurm et al. (1982-English Translation) specifically taught that "All flavonoids, regardless of the stereochemistry and degree of oxidation of their heterocyclic rings, are prostaglandin synthetase (PGS) inhibitors if at least one ring has a pyrocatechol structure" (pp. 6, English Translation). Cyanidin as well as anthocyanins (and bioflavanoids such as luteolin) fit Wurm et al's flavonoid description, as evidenced by the structure of cyanidin given by Lietti et al. (Please see structure on p.1). One of ordinary skill in the art would have had a reasonable expectation that cyanidin, although not specifically mentioned by Wurm et al., would have inhibited prostaglandin synthase.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art to inhibit prostaglandin synthesis and/or cyclooxygenase activity whereby inactivation of such activity is subsequent to decreased inflammation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive

effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Any mixture of the components embraced by the claims which does not exhibit an unexpected result is therefore obvious.

One of ordinary skill in the art would have reasonably ascertained that the phytochemicals proposed by Lietti et al. which were useful for treating conditions such as inflammation would have beneficially effected a human. One would have had a reasonable expectation of success because Lietti et al. clearly demonstrated that the anthocyanidins were useful in animals (Claim 16 for example), and consequently because animals were an acceptable model for human inflammation at the time the invention was made.

Claims which are specific as to the origin of the cyanidin do not materially change the method claim. It would have been obvious, in light of the teachings of Wurm et al. to have used cyanidin/anthocyanidin/bioflavanoid from any source because it was known that flavonoids with pyrocatechol structures were PGS inhibitors. Moreover, it was readily known that cyanidin was obtainable from cherries as readily admitted by Applicants.

It would have been further obvious to have incorporated cyanidin, a known PGS inhibitor into a formulation comprising carriers or mixtures of different flavanoids such as anthocyanins in different ratios, because, again, it was already known that flavonoids, with structures such as cyanidin inhibited PGS. Furthermore, claims to where the active ingredient is further included in a carrier and/or food does not materially change the method for inhibiting prostaglandin synthase or cyclooxygenase. The method is deemed to be the same method because the active ingredient in

the present case is cyanidin. Hence, it would have been obvious to have administered cyanidin in any form, with a carrier, or with food because it was already known that phytochemicals with pyrocatechol structures inhibited PGS alone. Thus, the addition of food and/or carriers would have required nothing more than routine randomization of result effective variables.

Varying individual levels of constituents in a pharmaceutical preparation was considered routine experimental procedure at the time of the instant invention. One of ordinary skill in the art would have been motivated to have modified the proportions of active ingredients in the composition in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment. Making such variations was deemed merely optimization of result effective variables, common in the art of pharmacology.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jon P. Weber, Ph.D.
Primary Examiner